

## **REMARKS**

Applicant notes that Claims 1-2, 9, 14, 16, 17, 19-21, 24-27, 29-31, 34, 36, 38, 42-45, 47, 49 and 90 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Goetz et al. (U.S. Patent No. 6,421,650, "Goetz") in view of Lion (U.S. Patent No. 6,330,491, "Lion"), and further view of Engelson et al. (U.S. Patent No. 6,671,563, "Engelson"). Claims 3-8, 22, and 28 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Goetz in view of Lion, in view of Engelson, and further in view of Edelson et al. (U.S. Patent No. 5,737,539, "Edelson"). Claims 89 and 91 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Goetz in view of Simcox et al. (U.S. Patent No. 5,992,890, "Simcox"), and further in view of Engelson. Applicant traverses these rejections for at least the following reasons.

In the most recent Office Action, the Examiner denied Applicant's previous arguments, arguing that the claims of the present application did not require that a prescribing physician be the source of the over-ride, such that the suggestion of such an over-ride in Engelson disclosed the broadest construction of the claims.

Applicant has herein amended claims 1, 20, 25, 27, 29, 36, 38, 45, 47, 49, 89, and 91 to clarify that the over-ride is received from a prescribing physician.

### **35 U.S.C. § 103(a) Rejections**

Claims 1-2, 9, 14, 16, 17, 19-21, 24-27, 29-31, 34, 36, 38, 42-45, 47, 49 and 90 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Goetz in view of Lion and further in view of Engelson. Claims 3-8, 22, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Goetz in view of Lion, in view of Engelson and further in view of Edelson. Claims 89 and 91 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Goetz in view of Simcox, and in further view of Engelson. Claims 1, 20, 25, 36, 38, 45, 47, 49, 89, and 91 are independent claims. Claims 2, 9, 14, 17, 19, 21, 24, 26-27, 29-31, 34, 42-44, and 90 accordingly each depend from one of the above independent claims.

35 U.S.C. § 103(a) recites:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

To establish obviousness, the scope and content of the prior art must first be determined. Second, the differences between the prior art and the claims at issue must be ascertained. Third, the level of ordinary skill in the relevant art must be determined. Finally, taking this background into consideration, the obviousness of the subject matter is determined. Secondary considerations such as commercial success, long felt but unsolved needs, failure of others, etc., can be utilized to determine the circumstances surrounding the origin of the subject matter

sought to be patented. *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), M.P.E.P. § 2141.

The Examiner has sought to demonstrate the obviousness of the claimed invention by combining those references to substantiate disclosure of each of the limitations of the claims. References may be combined when there exists a teaching or suggestion to combine the references to arrive at the claimed invention. While the Supreme Court has loosened the teaching/suggestion/motivation requirement, each limitation must still be somewhere disclosed, and there still must be some reason for combining the references (i.e., the references are all in the same field in which the function was made, such that they would be known to a person of ordinary skill in the art to which the invention pertains.

Claim 1 of the present invention relates to prescriptions, and, more particularly, to systems and methods for overriding a drug use evaluation alert, for capturing a reason for overriding a drug use evaluation alert, and for capturing and transmitting to a pharmacy or a claims processor a reason why a drug is to be dispensed as written. Claim 1 as currently amended requires that a prescribing physician, while actively involved in the task of prescribing medication, articulate and enter a reason for overriding a drug use evaluation alert via the graphical user interface provided by the electronic prescription device, thus, alleviating the need for prescriber verification of drug use evaluation alerts. Similarly, independent claims 20, 25, 36, 38, 45, 47, 49, 89, and 91 require that a prescribing physician, while actively involved in the task of prescribing medication, articulate and enter a reason for overriding a drug use evaluation alert via the graphical user interface provided by the electronic prescription device, thus, alleviating the need for prescriber verification of drug use evaluation alerts. The rejection of independent claims 1, 20, 25, 30, 45, 47, 49, 89, and 91 are discussed further below.

The Examiner notes that “Goetz and Lion do not disclose entering a reason for overriding the drug use evaluation alert.” The Examiner asserts that Engelson discloses this limitation. Engelson, however, is directed towards a “point-of-care management system” that utilizes nursing stations located in a hospital or clinic and provides an “on-line, real-time, patient specific graphical medication administration record” that reflects the current disposition of the *administration* of medication to the patient. Engelson, Col. 7, lines 57-64. The disclosure in Engelson shows a medication administration module that “allows a nurse to acknowledge and correct the discrepancy [regarding drug administration] in real-time, or override the alert by entering the appropriate command.” Engelson, Col. 9, lines 17-20. Engelson further discloses that a nurse will be allowed to override an alert generated *because of* a discrepancy in *drug administration* caused by the nurse’s actions, i.e., why the nurse failed to administer the prescribed medication. It must be noted that the nurse is not responsible for the prescription itself, let alone applying professional judgment as to whether a drug use evaluation alert should be overridden. Engelson, Col. 9, lines 13-24. Upon overriding the alert *caused by* the nurse’s decision to not *administer* a medication, the nurse is prompted to enter a reason for each alert override. Engelson, Col. 9, lines 20-24.

Prompting a nurse to explain why prescribed medication was not administered, based on real-time, in-hospital data, is clearly distinguishable from the present invention. Nothing in Engelson creates a link between the actions of a *prescribing physician* and the aforementioned medication administration record. Rather, Engelson links the actions of an *administrator* to the interactions made with the medication administration module. This is specifically demonstrated by the language in Engelson, as follows,

when a physician attending a patient diagnoses an illness and determines an appropriate course of treatment for the patient, the physician may prepare a

handwritten medical order specifying the desired therapeutic treatment as well as any appropriate parameters such as dosage and/or period of administration. The written prescription is sent through the institutional mail system to the pharmacy where it is then entered into the pharmacy information system 20 through a dedicated terminal, or other means, and is then entered into the care management system.

Engelson, Col. 7, lines 25-34. Clearly, Engelson does not teach the prescribing physician providing a reason overriding a drug use evaluation due to a discrepancy occurring during the act of prescribing which is a completely different role (i.e., professional judgment against administration tracking.). Engelson cannot, therefore, render claim 1 of the present invention obvious. Each of the independent claims 20, 25, 30, 45, 47, 49, 89, and 91, articulate the same limitations as claim 1 and the Examiner's objections regarding them are traversed by the above.

Furthermore, in order for Engelson to be considered a valid reference, it must be a reference that a person of ordinary skill in the art would consider, with respect to the claimed invention. Engelson is directed towards administration tracking in a hospital, not the decisions underlying the prescribing of medication.

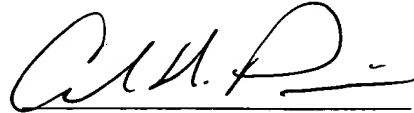
Claims 2, 14, 17, and 19 are each dependent on claim 1, and accordingly incorporate each of the limitations of claim 1. Claims 3-9 are also dependent on claim 1, and accordingly incorporate each of the limitations of claim 1. Claims 21, 22, 24-29, 30, 31, 34, 40, 42-44, and 90 are each claims dependent independent claims asserting the same limitations as claim and the Examiner's objections are similarly traversed.

Therefore, Applicant respectfully requests that the rejections under 35 U.S.C. § 103(a) with respect to claims 1, 20, 25, 30, 45, 47, 49, 89, and 91 be withdrawn.

**CONCLUSION**

Applicant respectfully submits that this application is not in condition for allowance and  
Applicant respectfully requests the same at the earliest possible time.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'C.H. Pierce', written over a horizontal line.

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